PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6: A61B 5/00 — A1

(11) International Publication Number: WO 97/00041

(43) International Publication Date: 3 January 1997 (03.01.97)

(21) International Application Number: PCT/US96/10296

(22) International Filing Date: 12 June 1996 (12.06.96)

(30) Priority Data:
08/490,315 14 June 1995 (14.06.95) US

(71) Applicant: NELLCOR PURITAN BENNETT INCORPORATED [US/US]; 4280 Hacienda Drive, Pleasanton, CA 94588 (US).

(72) Inventor: YORKEY, Thomas, J.; 3072 Bernard Avenue, San Ramon, CA 94583 (US).

(74) Agent: GLAUBENSKLEE, Marilyn; Nellcor Puritan Bennett Incorporated, Legal Dept., 4280 Hacienda Drive, Pleasanton, CA 94588 (US).

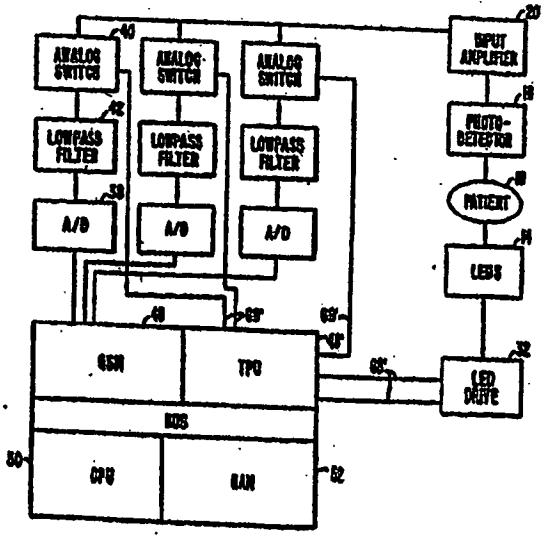
(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACT AND NOISE FROM PULSE OXIMETRY

(57) Abstract

Motion compensation is based on analysis of intensity signals received by detectors, without separately measuring a motion signal, without providing feedback to cancel the motion signal and without attempting to mathematically eliminate the motion signal. Instead, the present invention mathematically recognizes the presence of the motion signal and recognizes a few key characteristics of the motion signal and makes corresponding assumptions. First, it is recognized that the motion/noise in each wavelength signal is proportional. Second, it is assumed that the blood pulse signal is not affected by motion.



BEST AVAILABLE COPY

MAS 105168
CONFIDENTIAL
ATTORNEYS EYES ONLY

JOINT EXHIBIT JTX-3668 CV-00-6506 MRP

M 2409

Copied from 10779033 on 07/15/2005

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia
AT	Austria
AU	Australia
BB	Barbados
BE	Belgium
BF	Burkina Faso
BG	Bulgaria
BJ	Benin
BR	Brazil
BY	Belarus
CA	Canada
CF	Central African Republic
CG	Congo
CH	Switzerland
CI	Côte d'Ivoire
CM	Cameroon
CN	China
CS	Czechoslovakia
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GA	Gabon
GB	United Kingdom
GE	Georgia
GN	Guinea
GR	Greece
HU	Hungary
IE	Ireland
IT	Italy
JP	Japan
KE	Kenya
KG	Kyrgyzstan
KP	Democratic People's Republic of Korea
KR	Republic of Korea
KZ	Kazakhstan
LI	Liechtenstein
LK	Sri Lanka
LR	Liberia
LT	Lithuania
LU	Luxembourg
LV	Latvia
MC	Monaco
MD	Republic of Moldova
MG	Madagascar
ML	Mali
MN	Mongolia
MR	Mauritania
MW	Malawi
MX	Mexico
NE	Niger
NL	Netherlands
NO	Norway
NZ	New Zealand
PL	Poland
PT	Portugal
RO	Romania
RU	Russian Federation
SD	Sudan
SE	Sweden
SG	Singapore
SI	Slovenia
SK	Slovakia
SN	Senegal
SZ	Swaziland
TD	Chad
TG	Togo
TJ	Tajikistan
TT	Trinidad and Tobago
UA	Ukraine
UG	Uganda
US	United States of America
UZ	Uzbekistan
VN	Viet Nam

MAS 105169
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2410

Copied from 10779033 on 07/15/2005

METHOD AND APPARATUS FOR REMOVING MOTION ARTIFACT AND NOISE FROM PULSE OXIMETRY

BACKGROUND

The present invention relates to a pulse oximeter for detecting blood oxygenation, and in particular to the elimination of motion artifact which may affect the detected blood oxygenation signal.

Pulse oximeters typically measure and display various blood flow characteristics including but not limited to blood oxygen saturation of hemoglobin in arterial blood, volume of individual blood pulsations and the rate of blood pulsations corresponding to each heartbeat of the patient. The oximeters pass light through human or animal body tissue where blood perfuses the tissue such as a finger, an ear, the nasal septum or the scalp, and photoelectrically sense the change in absorption of light in the tissue. The amount of light absorbed is then used to calculate the amount of blood constituent being measured.

The light passed through the tissue is selected to be of one or more wavelengths that is absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of transmitted light passed through the tissue will vary in accordance with the changing amount of blood constituent in the tissue and the related light absorption.

The optical signal can be degraded by both noise and motion artifact. One source of noise is ambient light which reaches the light detector. Another source of noise would be electromagnetic coupling from other electronic instruments in the area. Motion of the patient can also affect the signal. For instance, when moving, the coupling between the detector and the skin or the emitter and the skin can be affected, such as by the detector moving away from the skin temporarily, for instance. In addition, since blood is a fluid, it may not move at the same speed as the surrounding tissue, thus

MAS 105160
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2411

JA 29089

Copied from 10779033 on 07/15/2005

resulting in a momentary change in volume at the point the oximeter probe is attached.

Such motion can degrade the signal used for making medical decisions, with the clinician being unaware of it. This is especially true if there is remote monitoring of the patient, the motion is too small to be observed, the clinician is watching the instrument or other parts of the patient and not the sensor site, or in a fetus where motion is hidden.

In one oximeter system described in U.S. Patent No. 5,025,791, an accelerometer is used to detect motion. When motion is detected, readings influenced by motion are either eliminated or indicated as being corrupted. In a typical oximeter, measurements taken at the peaks and valleys of the blood pulse signal are used to calculate the desired characteristic. Motion can cause a false peak, resulting in a measurement having an inaccurate value and one which is recorded at the wrong time. In U.S. Patent No. 4,802,486, assigned to Nellcor, the disclosure of which is incorporated herein by reference, an EKG signal is monitored and correlated to the oximeter reading to provide synchronization to limit the effect of noise and motion artifact pulses on the oximeter readings. This reduces the chances of the oximeter locking on to a periodic motion signal. Still other systems, such as that set forth in U.S. Patent No. 5,078,136, assigned to Nellcor, the disclosure of which is incorporated herein by reference, use signal processing in an attempt to limit the effect of noise and motion artifact. The '136 patent, for instance, uses linear interpolation and rate of change techniques to analyze the oximeter signal.

The nature of oximetry readings impose a number of difficulties in dealing with noise. The oximeter relies on mathematical analysis of the readings at two different wavelengths. Because different amounts of light are absorbed at each wavelength, the magnitude of the motion artifact due to the same motion will be different for each signal. This is complicated by the fact that the lights are alternately

MAS 105161
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2412

Copied from 10779033 on 07/15/2005

pulsed, and thus each is influenced by a different amount of motion, since the motion varies with time.

One system, set forth in PCT Publication No. WO 92/15955 (Vital Signals, Inc.) correlates the non-noise portion of two wavelength signals and generates a noise reference signal. The noise reference signal is then provided to an adaptive noise canceler to eliminate the noise from the desired signal.

Patent No. 4,714,341 discloses the use of three different wavelengths, rather than two, in order to detect when noise is present. This patent teaches using the first and second wavelength signals to produce a first oxygen saturation value, and then using the first and third wavelength signals to produce a second oxygen saturation value. The two calculated values are then compared. If the values are equal, as they should be absent motion, the signal is presumed to be good. If the values are different, the signal is assumed to contain motion and is disregarded.

SUMMARY OF THE INVENTION

The present invention is based on analysis of the signal intensity received by the detectors, without separately measuring the motion signal, without providing feedback to cancel the motion signal and without attempting to mathematically eliminate the motion signal. Instead, the present invention mathematically recognizes the presence of the motion signal and recognizes a few key characteristics of the motion signal. First, although the magnitude of the effect of motion on the signal intensity for each wavelength will be different, the change in the logarithm of the motion component will be approximately the same (for signals at approximately the same time). This allows the motion component to be cancelled out in a ratiometric equation. Second, it is assumed that the blood pulse signal is not affected by motion. This second assumption is more of an approximation, since the blood pulse signal is somewhat

MAS 105162
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2413

Copied from 10779033 on 07/15/2005

affected by motion, which can actually change the blood volume characteristics at any point in the patient.

The invention recognizes that the intensity signal for each of the wavelengths includes a time-varying motion term, and that this time-varying motion term is proportional for each of the wavelengths. In addition, each wavelength signal occurs close enough in time that the motion should not vary noticeably, and can assumed to be the same for each signal. Given this recognition, it is possible to determine the saturation by including an appropriate time-varying motion term in the equations to determine saturation. This can be done for either a two wavelength or a three wavelength embodiment.

In one two-wavelength embodiment, a time-variable motion term corresponding to motion noise is included in the equations representing the intensity for the first and second wavelength signals. The logarithm of each equation is taken, and then differentiated. The equations are then solved to determine the saturation value by assuming that the motion is a time varying function that is assumed to be independent of the concentration, and not vary in the time between signals.

In an alternate embodiment, radiation of three discrete, different wavelengths is directed through a portion of a patient. The amount of the radiation exiting the patient is detected for each of the three wavelengths, producing three intensity signals. Each intensity signal is represented by an equation which is a function of a saturation, the wavelength corresponding to the intensity signal and corresponding coefficients. In addition, a motion term is added to the equation which is assumed to be variable with time and is assumed to be the same for each of the different wavelength intensity signals. The three equations are then solved to determine the saturation value, preferably using matrix algebra.

For a fuller understanding of the nature and advantages of the invention, reference should be made to the

MAS 105163
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2414

Copied from 10779033 on 07/15/2005

ensuing detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1A-1D are diagrams of an intensity signal showing the effects of pulsatile flow and motion noise;

Figs. 2A and 2B are diagrams illustrating the effect of motion on the path length of emitted light, and thus on the intensity of received light; and

Fig. 3 is a block diagram of a system according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figs. 1A-1D illustrate aspects of a pulse oximeter signal which the present invention takes advantage of. Fig. 1A shows the logarithm of a detected infrared signal. Fig. 1B shows the logarithm of a detected red wavelength signal. For both of these figures, the signal includes motion occurring in the interval of 5-12 seconds. Otherwise, both the red and infrared signals are noise-free optical signals. Fig. 1C shows the result of a subtraction between the signals in Figs. 1A and 1B. As this illustrates, the subtraction cancels out the noise. This is because the data exists in logarithm form, and the motion corruption is additive. Accordingly, in addition to calculating saturation, the difference waveform (Fig. 1C) can be scaled, and then subtracted from either the logarithm of the IR or red signal to obtain an estimate of the motion noise. Fig. 1D shows this estimate.

Fig. 2A illustrates one possible example of how motion can effect the intensity signal. A light emitter 16 is shown emitting rays 18 through a patient's finger 20. This is detected by a detector 22. As can be seen, the distance from the emitter to the detector, D, will determine the amount of light emitted by the emitter reaching the detector, since there will be a natural spreading effect of non-collimated

MAS 105164
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2415

JA 29093

Copied from 10779033 on 07/15/2005

light rays. The farther away the detector is, the more spreading results.

Fig. 2B illustrates another example showing how motion of a finger can compress and widen the finger (exaggerated in the figure) and temporarily cause the light emitter 16 to move away from the detector an additional distance indicated by arrow 24. This additional distance will cause less of the light to reach the detector, since there will be more spreading of the light emitted at this larger distance. This will result in a lower intensity waveform being detected by the detector. Alternately, compression could result in a higher intensity waveform. Motion and noise can take other forms as well, and can vary for other reasons than non-collimated light rays. For instance, the emitter and detector could be slightly misaligned.

The present invention recognizes that the calculation for determining oxygen saturation by pulse oximetry using the "ratio of ratios" can be assumed to have a motion term which is independent of any particular wavelength. An understanding of this first requires an understanding of how the ratio of ratios is calculated.

Using Lambert-Beer's law as a starting point, equation (1) below is used to determine saturation in pulse oximetry:

$$I(\lambda, t) = I_o(\lambda) \exp(-(s\beta_o(\lambda) + (1-s)\beta_r(\lambda)) l(t)) \quad (1)$$

where:

λ = *wavelength*

t = *time*

I_o = *intensity of light transmitted*

I = *intensity of light detected*

s = *oxygen saturation*

β_o, β_r = *empirically derived absorption coefficients for oxygenated and deoxygenated hemoglobin, respectively*

$l(t)$ = *a combination of concentration and path length from emitter to detector as a function of time*

MAS 105165
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2416

Copied from 10779033 on 07/15/2005

The traditional approach is to solve for ratio of ratios and then calculate saturation.

Take natural logarithm of equation (1) for IR and Red:

$$\log I = \log I_o - (s\beta_o + (1-s)\beta_r) l \qquad (2)$$

Differentiate equation (2) with respect to time:

$$\frac{d\log I}{dt} = -(s\beta_o + (1-s)\beta_r)\frac{dl}{dt} \qquad (3)$$

Divide Red (3) by IR (3)

$$\frac{d\log I(\lambda_R)/dt}{d\log I(\lambda_{IR})/dt} = \frac{s\beta_o(\lambda_R) + (1-s)\beta_r(\lambda_R)}{s\beta_o(\lambda_{IR}) + (1-s)\beta_r(\lambda_{IR})} \qquad (4)$$

For a discrete time sample, equations of the above form can be rewritten by noting:

$$\frac{d\log I(\lambda, t)}{dt} = \log I(t_2, \lambda) - \log I(t_1, \lambda)$$

Using logA-logB = logA/B, the above equation can then be written as:

$$\frac{d\log I(\lambda)}{dt} = \log\left(\frac{I(t_2, \lambda)}{I(t_1, \lambda)}\right)$$

So,

$$\frac{\frac{d\log I(\lambda_R)}{dt}}{\frac{d\log I(\lambda_{IR})}{dt}} = \frac{\log\left(\frac{I(t_1, \lambda_R)}{I(t_2, \lambda_R)}\right)}{\log\left(\frac{I(t_1, \lambda_{IR})}{I(t_2, \lambda_{IR})}\right)} = R \qquad (5)$$

Where R is the "ratio of ratios."

MAS 105168
CONFIDENTIAL
ATTORNEYS EYES ONLY

Copied from 10779033 on 07/15/2005

Solving (4) for s using (5) gives:

$$s = \frac{\beta_r(\lambda_R) - R\beta_r(\lambda_{IR})}{R(\beta_o(\lambda_{IR}) - \beta_r(\lambda_{IR})) - \beta_o(\lambda_R) + \beta_r(\lambda_R)}$$

From (5) note R can be calculated using two points corresponding to measurements at two different times, t. Alternately, a family of points can be used. To see this latter point define:

$$x(t) = \log\left(\frac{I(t+\Delta t, \lambda_{IR})}{I(t, \lambda_{IR})}\right)$$

$$y(t) = \log\left(\frac{I(t+\Delta t, \lambda_R)}{I(t, \lambda_R)}\right)$$

Then, equation (5) can be written as:

$$y(t) = Rx(t)$$

and for a family of points over time this will describe a cluster of points that define a best-fit line of y versus x with a slope given by R.

The present invention modifies the above equations by recognizing that a term can be added to account for motion and noise. In particular, the motion and noise component can be represented by a function which varies with time and is wavelength-independent. This recognition allows a mathematical solution to isolate and eliminate the motion and noise components without requiring prior art methods such as separately measuring the motion.

Motion. For example, to account for motion and noise, we can modify equation (1) by multiplying by a time varying function $\eta(t)$ representing wavelength-independent motion or noise. This gives the following equation:

$$I(\lambda, t) = I_o(\lambda)\,\eta(t)\exp(-(s\beta_o(\lambda) + (1-s)\beta_r(\lambda))l(t)) \quad (6)$$

MAS 105167
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2418

Copied from 10779033 on 07/15/2005

We can then solve for s using the same steps as used above.

First, we take the logarithm:

$$\log I = \log I_o + \log\eta - (s\beta_o + (1-s)\beta_r)\, l$$

Next, we differentiate with respect to time:

$$\frac{d\log I}{dt} = \frac{d\log\eta}{dt} - (s\beta_o + (1-s)\beta_r)\frac{dl}{dt} \qquad (7)$$

Then, we determine the ratio of Red to IR:

$$\frac{d\log I(\lambda_R)/dt}{d\log I(\lambda_{IR})/dt} = \frac{d\log\eta/dt - (s\beta_o(\lambda_R) + (1-s)\beta_r(\lambda_R))\frac{dl}{dt}}{d\log\eta/dt - (s\beta_o(\lambda_{IR}) + (1-s)\beta_r(\lambda_{IR}))\frac{dl}{dt}}$$

Now if $d\log\eta/dt$ is large compare to the other terms the ratio of ratios will be driven towards unity, driving s towards a wavelength-dependant constant. So because in this model optical coupling due to motion appears identically in both wavelengths, its presence drives the saturation to this wavelength-dependant constant.

The present invention thus allows a calculation of blood oxygen saturation by mathematically recognizing the motion signal. This enables a solution which does not require separately measuring the motion signal, providing feedback to cancel the motion signal, or attempting to mathematically eliminate the motion signal. Set forth below are two preferred embodiments for implementing the present invention, one using three wavelengths of light and another using two wavelengths.

A Three-wavelength Solution

Let λ_o be some other wavelength (not IR or Red). Now take the logarithm and differentiate this third wavelength, obtaining (7). One approach might be to

MAS 105168
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2419

Copied from 10779033 on 07/15/2005

difference IR with this new wavelength, and similarly with Red. The problem with differencing is that R could become infinite when:

$$\frac{d}{dt}\log I(\lambda_{ir}) - \frac{d}{dt}\log I(\lambda_o) = 0.$$

Here is a better solution. Rewrite (7) as:

$$\frac{d\log I}{dt} = \frac{d\log \eta}{dt} + (\beta_r - \beta_o)\, s\frac{dI}{dt} - \beta_r \frac{dI}{dt}$$

Now to introduce some matrix algebra, define:

$$b_i = \frac{d}{dt}\log I(\lambda_i)$$

$$u = \frac{dI}{dt}$$

$$m = \frac{d}{dt}\log \eta$$

$$c_{1j} = \beta_r(\lambda_j) - \beta_o(\lambda_j)$$

$$c_{2j} = \beta_r(\lambda_j)$$

MAS 105169
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2420

Copied from 10779033 on 07/15/2005

With this notation

$$\begin{bmatrix} b_1 \\ b_2 \\ b_3 \end{bmatrix} = \begin{bmatrix} c_{11} & c_{21} & 1 \\ c_{12} & c_{22} & 1 \\ c_{13} & c_{23} & 1 \end{bmatrix} \begin{bmatrix} su \\ u \\ m \end{bmatrix}$$

$$b = Cx$$

$$x = C^{-1}b$$

$$s = x_1 / x_2$$

$$m = x_3$$

So as long as C is full rank, there is no difficulty in solving for saturation and the optical coupling terms uniquely. In other words, you can now solve for m exactly because there is no wavelength where $b_1 = b2 = b_3$ for a given saturation.

Note a calibration set of extinction coefficients are needed for this third wavelength, but also note that the best new wavelength is one that gives the highest condition number to C, which is not necessarily the isobestic point. The calibration coefficients for the third wavelength are constrained by the coefficients for the first two wavelengths. When there is no motion, the saturation calculated using two wavelengths and three wavelengths should be the same.

This optical coupling method will be less accurate when the lumped concentration path-length term becomes wavelength dependent, then the dependence no longer ratios away in calculating saturation. Also, there is no reason to believe that u will look anything like a typical pulse oximetry waveform during motion since path-length and concentration will be varying with the motion, and these effects will be seen in u, but s will still be the correct saturation.

MAB 105170
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2421

Copied from 10779033 on 07/15/2005

A Two-wavelength Solution

With two wavelengths we have:

$$\begin{bmatrix} b_1 \\ b_2 \end{bmatrix} = \begin{bmatrix} c_{11} & c_{21} & 1 \\ c_{12} & c_{22} & 1 \end{bmatrix} \begin{bmatrix} su \\ u \\ m \end{bmatrix} \quad (8)$$

Two equations and three unknowns. One approach is to return to calculating R by rewriting (8):

$$b_1 = v+m$$
$$b_2 = Rv+m$$

where m is the motion term, as defined earlier, R is the ratio of ratios, and v is the signal with no motion.

There are two key assumptions which make the solution possible. First, although the magnitude of the effect of motion on each intensity signal will be different, the change in the logarithm of the motion component at two different times will be the same (which assumes the different time signal samples are adjacent or close together in time). This allows the motion component to be cancelled out in a ratiometric equation. The second assumption is that the motion does not cause any effect on the remainder of the equation. There is some effect, since motion can change the pulse flow characteristics of the blood, but this is typically a small effect compared to the motion when there is significant motion present. By assuming that the motion has no effect on any elements of the concentration measurement, we assume that v and m are not related.

Another assumption is that the amount of motion is the same at the time of both intensity signal measurements for the two wavelengths. This is a reasonable assumption since the typical motion signal varies at a rate of around 1 Hz, while the light pulsing frequency is typically at a rate of 1200 Hz.

MAS 106171
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2422

JA 29100

Copied from 10779033 on 07/15/2005

Assuming v and m are independent over time, $(v,m)=0$ for some defined inner product. Substituting for v and m yields:

$$\left\langle \frac{b_2-b_1}{R-1}, \frac{b_2-Rb_1}{R-1} \right\rangle = 0$$

Solving for the R that solves this equality yields:

$$R = \frac{(b_2-b_1, b_2)}{(b_2-b_1, b_2)}$$

There are two problems with this approach.

When R approaches one, b_2-b_1 approaches zero, and the above equation approaches zero divided by zero. This fact is not in itself a total problem for when b_2-b_1 does approach zero you simply use $R=1$.

A more limiting problem is the assumption that $(v,m)=0$. Certainly the motion signal is independent of the arterial pulsatile signal, but during motion, v also has path-length concentration effects in it that are highly correlated with m, thus biasing R away from its true value.

Fig. 3 is a block diagram of one embodiment of a pulse oximeter implementing the present invention. Light from LEDs 14 passes into patient tissue 18, and after being transmitted through or reflected from tissue 18, the light is received by photosensor 16. Either two or three LEDs can be used depending upon the embodiment of the present invention. Photosensor 16 converts the received energy into an electrical signal, which is then fed to input amplifier 20.

Light sources other than LEDs can be used. For example, lasers could used, or a white light source could be used with appropriate filters either at the transmitting or receiving ends.

Time Processing Unit (TPU) 48 sends control signals 68 to the LED drive 32, to alternately activate the

MAS 105172
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2423

JA 29101

Copied from 10779033 on 07/15/2005

LEDs. Again, depending on the embodiment, the drive may control two or three LEDs.

The signal received from input amplifier 20 is passed through three different channels as shown in the embodiment of Fig. 3, for three different wavelengths. Alternately, two channels for two wavelengths could be used. Each channel includes an analog switch 40, a low pass filter 42, and an analog to digital (A/D) converter 38. Control lines 69 from TPU 48 select the appropriate channel at the time the corresponding LED 14 is being driven, in synchronization. A queued serial module (QSM) 46 receives the digital data from each of the channels. CPU 50 transfers the data from QSM 46 into RAM 52 as QSM 46 periodically fills up. In one embodiment, QSM 46, TPU 48, CPU 50 and RAM 52 are part of one integrated circuit, such as a DMC68HC16 microcontroller from Motorola.

The method of the present invention is practiced by CPU 50 on the data in RAM 52 as received through the various channels from photodetector 16. The signal from photodetector 16 is the signal which originated from LEDs 14, as reflected or transmitted by patient 18, and including undesired noise artifact.

As will be understood by those of skill in the art, the present invention can be embodied in other specific forms without departing from the spirit or essential characteristics thereof. For example, saturation could be determined using different mathematical calculations, once it is recognized that the motion term is a function of time that is independent of wavelength and is approximately the same for two adjacent in time signal samples at two different wavelengths. In one example, the mathematical determination could be done by dividing the two intensity equations to eliminate the motion term. Although this would only eliminate the motion from one wavelength equation, this could be done for alternate wavelengths in alternate samples. In a three wavelength embodiment, division of two separate pairs could be done to eliminate the motion signal. Accordingly, the disclosure of

MAS 105173
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2424

Copied from 10779033 on 07/15/2005

the preferred embodiment of the invention is intended to be illustrative, but not limiting, of the scope of the invention which is set forth in the following claims.

MAS 105174
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2425

Copied from 10779033 on 07/15/2005

WHAT IS CLAIMED IS:

1. A method for measuring saturation of a blood constituent in a patient comprising the steps of:

irradiating said patient with electromagnetic radiation of at least two discrete, different wavelengths;

sensing an intensity of said radiation for each of said wavelengths after it passes through a portion of said patient to produce first and second intensity signals; and

determining said saturation by manipulating said first and second intensity signals with the assumptions that

i) an amount of motion is the same at the same time for each of said intensity signals, and

ii) the motion components of said intensity signals are proportional to one another.

2. The method of claim 1 wherein said determining step assumes that the derivative of the logarithms of the motion components of said intensity signals are the same.

3. The method of claim 1 further comprising the steps of:

representing each of said intensity signals as a function of said saturation, the wavelength corresponding to the intensity signal, and a time-variable motion term corresponding to motion noise, said motion terms being proportional to one another for each of said intensity signals;

taking the logarithm of each representation of said first and second intensity signals;

differentiating each logarithm;

equating the first differentiated logarithm of the first intensity signal to v + m, where m is the portion of the signal due to motion;

MAS 105176
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2426

Copied from 10779033 on 07/15/2005

equating the second differentiated logarithm of the second intensity signal to Rv + m, where R is a ratio of first and second wavelength ratios, each wavelength ratio being the logarithm of the ratio of the intensity signal for the wavelength at first and second times;

expressing said representations as a matrix;

solving said matrix for R by assuming v and m are independent for some defined inner product; and

determining said saturation from R.

4. The method of claim 3 further comprising the step of displaying said saturation on a monitor.

5. The method of claim 4 further comprising the step of activating an alarm if said saturation is less than a predetermined amount for a predetermined period of time.

6. The method of claim 1 further comprising the steps of:

irradiating said patient with electromagnetic radiation of at least three discrete, different wavelengths;

sensing the intensity of said radiation for each of said wavelengths after it passes through a portion of said patient to produce first, second and third intensity signals;

representing each of said intensity signals as a function of said saturation, the wavelength corresponding to the intensity signal, and a time-variable motion term corresponding to motion noise, said motion terms being proportional to one another for each of said intensity signals; and

solving the three functions to obtain a value for said saturation.

MAS 105178
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2427

Copied from 10779033 on 07/15/2005

7. The method of claim 1 wherein said determining step assumes that the derivative of the logarithm of the motion component of each intensity signal is the same.

8. The method of claim 6 wherein each of said functions includes a plurality of coefficients, and further comprising the step of determining a set of coefficients for said third intensity signal from a measurement in the absence of motion noise and a determination of said saturation from said first and second intensity signals.

9. The method of claim 6 further comprising the steps of:

taking the logarithm of each representation of said first, second and third intensity signals;

differentiating each logarithm;

putting the differentiated logarithms into a matrix; and

solving said matrix for said saturation.

10. A method for measuring the saturation of a blood constituent in a patient comprising the steps of:

irradiating said patient with electromagnetic radiation of three discrete, different wavelengths;

sensing the intensity of said radiation for each of said wavelengths after it passes through a portion of said patient to produce first, second and third intensity signals;

representing each of said intensity signals as a function of said saturation, the wavelength corresponding to the intensity signal, and a time-variable motion term corresponding to motion noise, said motion term being the same for each of said intensity signals; and

solving the three functions to obtain a value for said saturation.

MAS 108177
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2428

Copied from 10779033 on 07/15/2005

11. The method of claim 10 wherein each of said functions includes a plurality of coefficients, and further comprising the step of determining a set of coefficients for said third intensity signal from a measurement in the absence of motion noise and a determination of said saturation from said first and second intensity signals.

12. The method of claim 10 further comprising the steps of:

taking the logarithm of each representation of said first, second and third intensity signals;

differentiating each logarithm;

putting the differentiated logarithms into a matrix; and

solving said matrix for said saturation.

13. A method for measuring the saturation of a blood constituent in a patient comprising the steps of:

irradiating said patient with electromagnetic radiation of two discrete, different wavelengths;

sensing the intensity of said radiation for each of said wavelengths after it passes through a portion of said patient separately to produce first and second intensity signals;

representing each of said intensity signals as a function of said saturation, the wavelength corresponding to the intensity signal, and a time-variable motion term corresponding to motion noise, said motion term being the same for each of said intensity signals;

taking the logarithm of each representation of said first and second intensity signals;

differentiating each logarithm;

equating the first differentiated logarithm of the first intensity signal to v + m, where m is the portion of the signal due to motion;

MAS 105178
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2429

Copied from 10779033 on 07/15/2005

equating the second differentiated logarithm of the second intensity signal to Rv + m, where R is a ratio of first and second wavelength ratios, each wavelength ratio being the logarithm of the ratio of the intensity signal for the wavelength at first and second times;

expressing said representations as a matrix;

solving said matrix for R by assuming v and m are independent for some defined inner product; and

determining said saturation from R.

14. An apparatus for measuring the saturation of a blood constituent in a patient comprising:

first and second emitters, said emitters emitting radiation of first and second different wavelengths;

a detector for sensing the intensity of said light, said detector being mounted relative to said first and second emitters so that said light is detected after it passes through a portion of said patient;

a controller for alternately activating said emitters so that said detector detects the different wavelengths at different times to produce first and second intensity signals; and

control means for determining said saturation by manipulating said first and second intensity signals with the assumptions that

i) an amount of motion is the same at the same time for each of said intensity signals, and

ii) the motion components of said intensity signals are proportional to one another.

15. The apparatus of claim 14 wherein said control means further comprises means for assuming that the derivative of the logarithm of the motion components are the same.

MAS 106179
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2430

Copied from 10779033 on 07/15/2005

16. The apparatus of claim 14 wherein said apparatus is a pulse oximeter and said control means further comprises:

means for representing each of said intensity signals as a function of said saturation, the wavelength corresponding to the intensity signal, and a time-variable motion term corresponding to motion noise, said motion term being the same for each of said intensity signals;

means for taking the logarithm of each representation of said first and second intensity signals;

means for differentiating each logarithm;

means for equating the first differentiated logarithm of the first intensity signal to v + m, where m is the portion of the signal due to motion;

means for equating the second differentiated logarithm of the second intensity signal to Rv + m, where R is a ratio of first and second wavelength ratios, each wavelength ratio being the logarithm of the ratio of the intensity signal for the wavelength at first and second times;

means for expressing said representations as a matrix;

means for solving said matrix for R by assuming v and m are independent for some defined inner product; and

means for determining said saturation from R.

17. The apparatus of claim 14 further comprising a display, coupled to said control means, for displaying said saturation.

18. The apparatus of claim 17 further comprising an alarm coupled to said control means for indicating when said saturation is less than a predetermined amount for a predetermined period of time.

MAS 105180
CONFIDENTIAL
ATTORNEYS EYES ONLY

Copied from 10779033 on 07/15/2005

19. The apparatus of claim 14 further comprising:

a third emitter for irradiating said patient with electromagnetic radiation of a third discrete, different wavelength;

said controller alternately activating said first, second and third emitters so that said detector produces first, second and third intensity signals;

said control means including

means for representing each of said intensity signals as a function of said saturation, the wavelength corresponding to the intensity signal, and a time-variable motion term corresponding to motion noise, said motion term being the same for each of said intensity signals; and

means for solving the three functions to obtain a value for said saturation.

MAS 105161
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2432

Copied from 10779033 on 07/15/2005

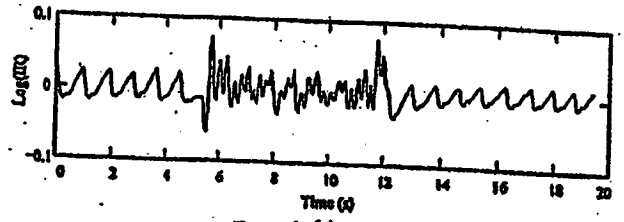


FIG. 1 (a)

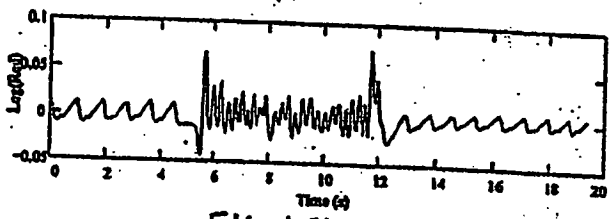


FIG. 1 (b)

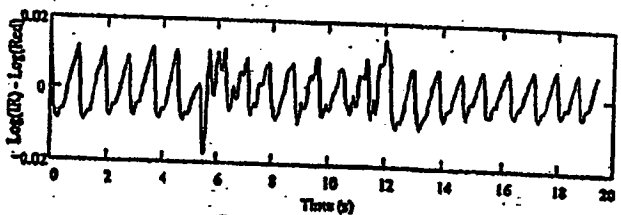


FIG. 1 (c)

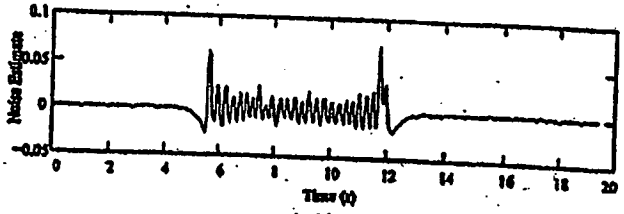


FIG. 1 (d)

MA8 105182
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2433

Copied from 10779033 on 07/15/2005

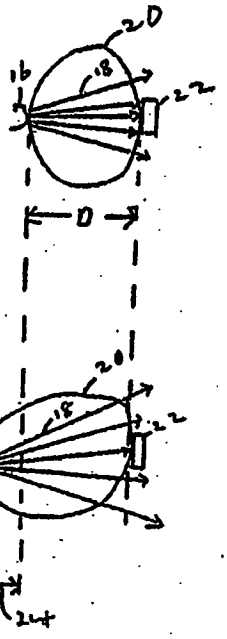


FIG. 2A

FIG. 2B

MAB 105163
CONFIDENTIAL
ATTORNEYS EYES ONLY

Copied from 10779033 on 07/15/2005

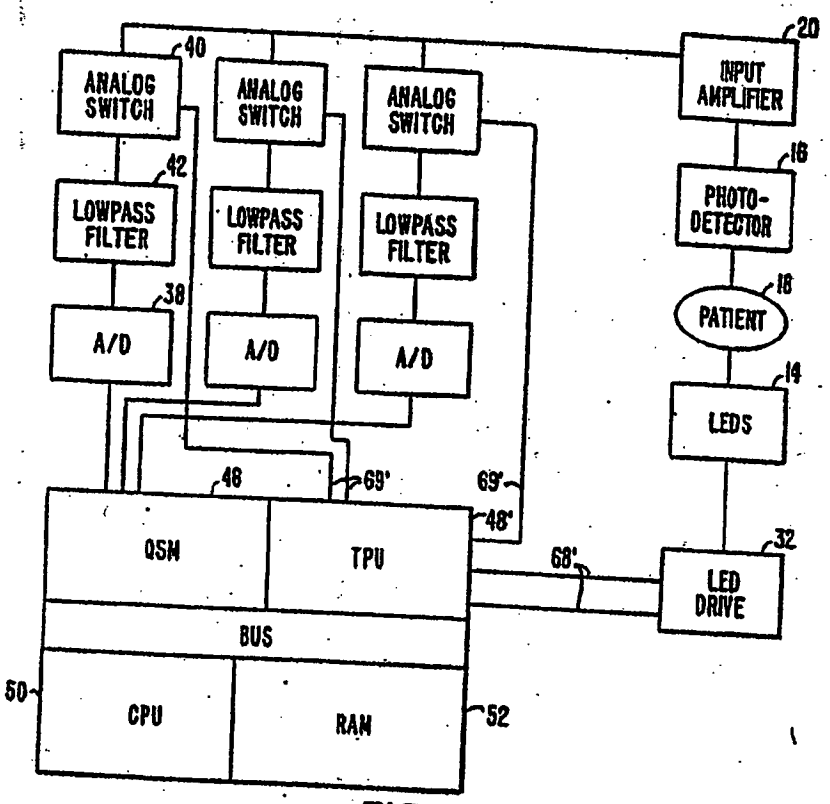


FIG. 3

MAS 106184
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2435

Copied from 10779033 on 07/15/2005

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/10296

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B G01N G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,94 03102 (UNIV SWANSEA ;PARKER DAWOOD (GB)) 17 February 1994 see the whole document	1,6,10
Y		2,7, 13-16,19
Y	US,A,5 351 685 (POTRATZ ROBERT S) 4 October 1994 see the whole document	2,7, 13-16,19
A		1,10,14
A	US,A,4 167 331 (NIELSEN LARRY L) 11 September 1979 see the whole document	1-3,6, 10, 12-14, 16,19

-/--

[X] Further documents are listed in the continuation of box C. [X] Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search
7 October 1996

Date of mailing of the international search report
14. 11. 96

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer
Ferrigno, A

Form PCT/ISA/210 (second sheet) (July 1992)

MA8-105185
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2436

JA 29114

Copied from 10779033 on 07/15/2005

INTERNATIONAL SEARCH REPORT

Inter tal Application No
PCT/US 96/10296

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE,A,36 29 447 (CRITICARE SYSTEMS INC) 9 April 1987 see the whole document -----	1,3-5, 10,13, 14,17,18

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

MAS 105186
CONFIDENTIAL
ATTORNEYS EYES ONLY

Copied from 10779033 on 07/15/2005

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 96/10296

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-13
because they relate to subject matter not required to be searched by this Authority, namely:
See additional sheet.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

MAS 105187
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2438

Copied from 10779033 on 07/15/2005

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US 96/10296

FURTHER INFORMATION CONTINUED FROM PCT/ISA/210

The subject-matter of claims 1-13 relates to a diagnostic method carried out on the living human body. According to Rule 39 and Article 17 PCT, no International Search is required for such a subject-matter. An incomplete search has been therefore carried out for claims 1-13: the search has been limited to the "means" for carrying out the claimed method. Claims 14-19 have been searched completely.

MAS 105168
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2439

Copied from 10779033 on 07/15/2005

INTERNATIONAL SEARCH REPORT

information on patent family members

Interna al Application No
PCT/US 96/10296

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9403102	17-02-94	AU-A-	4719893	03-03-94
		ZA-A-	9305579	02-02-94
US-A-5351685	04-10-94	US-A-	5533507	09-07-96
US-A-4167331	11-09-79	DE-A-	2756462	22-06-78
		JP-C-	1345150	29-10-86
		JP-A-	53088778	04-08-78
		JP-B-	61011097	01-04-86
DE-A-3629447	09-04-87	JP-A-	62109547	20-05-87

Form PCT/ISA/210 (patent family annex) (July 1992)

MAS 105189
CONFIDENTIAL
ATTORNEYS EYES ONLY

M 2440

Copied from 10779033 on 07/15/2005

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.
As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.

Copied from 10779033 on 07/15/2005